Health Workforce Pilot Projects Program
Facility-Based Assessment Form
171—07-200
San Diego, California

Elements of Implementation	Regulation Compliance			Factors Considered	Assessment Remarks					
	Met	Not Met	N/A		BRN	MBC	Assoc. of Reproductive Health Professionals	American College of OB-GYN, District IX	Technical Consultant - UCD FNP/PA Program	OSHPD-HWPP
Regulation: (Section 92304). Sponsor Information. Sponsor information shall include, but not be limited to the following: (d) Description of funding sources for the project. (f) Composition of Advisory Group (g) An identification of collaborative arrangements with other educational clinical phase. This would include the availability of support services such as library, equipment, etc.				Funding source documentation. (FY and amount) Advisory Group and meeting outcomes Contract: Sponsor w/participating facility. Sponsor and health care facility relationship. Organizational chart to reflect the working relationship of trainee to supervisor Contract or MOU with a general acute care hospital for emergency protocols, post procedure admissions.	<u>Procedure Report</u> We need to know that the informed consent, i.e. actual procedures were completed; any complications.	No report received.	Not present.	I was surprised to learn that it is already considered within the current scope of practice for mid-level providers to perform suction aspirations for non-viable pregnancies (miscarriages, incomplete abortions etc.). This assertion was made by the study coordinator and she indicated that this was current practice (outside of the study) in the Shasta area. We would ask the Board of Registered Nursing (BRN) to confirm that this is indeed the case and provide us a statement that we can share with our members. Obviously if this is outside their scope of practice we would ask the Board of Nursing to take appropriate action to prevent this from taking place outside the scope of the study. There was discussion	This visit was focused on interviews of Advanced Practice Clinician (APC)/Trainees, Preceptor, Clinical Administrators and members of the Research Team. Due to very strict confidentiality protocols, clinical documentation was reviewed on site and not removed from the site. This area has 2 training sites in Riverside and San Diego. There are 4 clinicians who have completed the core training and are in clinical practice phase	The San Diego/Riverside program has 2 sites, one in each city. Combined there are 4 trainees 1 preceptor and 1 other MD available to assist the preceptor. One trainee is located at the Riverside site.

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								about some of the procedures in the Shasta area being performed at satellite sites by midlevel providers without physicians on site. We want to make sure that if this indeed is the case that the facilities have all the necessary safety precautions in place to care for a complication, specifically written transfer agreements and other safety requirements of Title 22. While I know you stated that OSHPD can waive Title 22 requirements for the study I suspect that you did not intend to waive those provisions related to patient safety.		
Regulation: (Section 92312) Modifications. Any modifications or additions to approved project: (a) Change in scope of project (b) Change in selection criteria for: trainees, supervisors or employment/utilization sites, project staff or instructors, curriculum, other. (c) Change in project staff or instructors										

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Regulation: (Section 92305), (Section 92311). Trainee Information. Plan to inform trainees of their responsibilities and limitations under the Health Workforce Pilot Project statutes and regulations. (a) Name, work address and telephone number of the trainee. (b) Name, work address of the supervisor. and telephone number and license number				Training Agreement. Public disclosure document regarding availability of trainee information. Listing of trainees and supervisors per participation site - license information.	Standardized Procedures. When using the language licensed nurse practitioner, it should be changed to certified nurse practitioner.					Note: The HWPP #171 sponsor asks that we sign a confidentiality statement for purposes of not disclosing participant names. Cleared by OSHPD legal to sign agreement.
Regulation: (Section 92306). Curriculum. (a) A description of the minimum level of competence the trainee shall achieve before entering the employment/utilization phase of the project. (b) A description of the content required to meet this minimal competency. (c) A description of the methodology utilized in the didactic and clinical phases. (d) A description of the evaluation process used to determine when trainees have achieved the minimum level of competence. (e) An identification in hours and months of the time required to complete the didactic and clinical phases.				Curriculum Availability. Descriptions of: Observed Performance Assessment; Procedure Log; Patient Complications Tracking; Trainee Clinical Schedule.					Reviewed the APC Guidelines and Protocols along with BRN. We found them to be complete and clear. Issues that were discussed in general were that the curriculum is competency based and there is a process that has been developed to attain competency. The numbers of procedures are not as important to patient safety as is the competency of the clinician in the procedure. The site has a method to	The sites curriculum and protocols were available for review. Two of the team members reviewed them. OSHPD has the curriculum in-house.

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									continually evaluate competency through all aspects of the training module	
Regulation: (Section 92101). Minimum Standards. Each Pilot project shall: (a) Provide for patient safety. (b) Provide qualified instructors to prepare trainees. (e) Demonstrate that the project has sufficient staff to monitor trainee performance and to monitor trainee supervision during the employment/utilization phase. (g) Demonstrate the feasibility of achieving the project objectives.				Clinical protocols including management of emergencies related to callbacks, general acute hospital care admissions and post care. Listing of trainees and supervisors per participation site - license information.			.	I am concerned that the follow up rate is only about 70%. Since the complication rate for abortions is low to begin with (generally less than 5%) missing even a few complications due to failure to get follow up has the chance to significantly affect the results. I found it interesting that some of the providers stated they had not had any complications throughout the trial to date. I suspect this reflects inadequate follow up rather than perfect technique and outcomes.	The Project has studied patient outcomes including patient satisfaction. Patients are given a choice between the APC and physician - 30% declined APC. There is a standardized method used to track all adverse events relative to the procedure and follow up care. Patient satisfaction between APC and physician were the same.	
Regulation: (Section 92308). Monitoring (a) A description of the provisions for protecting patients' safety. (b) A description of the methodology used by the project director and project staff to provide at				Review: chart and quality management reviews. Observed performance				There seems to be a difference in skills and comfort level among the providers which is to be expected in any training system.		Patient satisfaction abstract summaries were made available for the team to review.

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least quarterly monitoring of the following: (1) Trainee competency. (2) Supervisor fulfillment of role and responsibilities (3) Employment/utilization site compliance with selection criteria.				assessment. Procedure Log. Patient complications tracking trainee clinical schedule. Skills and experience inventory assessment forms. Clinical Satisfaction - Staff surveys. (quarterly review)				Some providers are doing these procedures independently without a physician on site after their initial 40 cases while others stated they do not feel comfortable doing them without a physician immediately available even after performing nearly 100 cases. I believe having a physician immediately available on site is necessary to provide adequate support for all the mid-level providers, regardless of their confidence level as well as providing an appropriate level of safety for patients. While I am aware that the study allows for providers to perform abortions without a provider on site after completion of the initial 40 cases, I believe these procedures (done without a physician on site) in particular need to be carefully scrutinized and have meticulous follow up to demonstrate safety if this study is to be used to consider a change in the scope of practice of		Abstract summaries of trainee's performance were also made available for the team to review.

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								mid-level providers.		
Regulation: (Section 92309). Informed Consent. The plan used to obtain prior informed consent from patients to be treated by trainees or those legally able to give informed consent for the patients shall be described. It shall include, but not be limited to the following: (a) A description of the content of the informed consent. (1) Explanation of the role and status of the trainee, including the ready availability of the trainee's supervisor for consultation. (2) Assurance that the patient can refuse care from a trainee without penalty for such a request. (3) Identification that consenting to treatment by a trainee does not constitute assumption of risk by the patient. (b) Provision that the content of the informed consent, either written or oral, shall be provided in a language in which the patient is fluent. (c) Documentation in the patient record that informed consent has been obtained prior to providing care to the patient. (d) Provision for obtaining witnesses to informed consent. Written informed consent must be witnessed. Oral informed consent obtained by the trainee shall have a third party document in writing that he/she has witnessed the oral consent. (e) Informed consent need be obtained only for those tasks, services, or functions to be provided as a pilot project trainee.				Informed consent form- signed by patient or patient representative.						The sponsor indicated that they consent to patients in English and Spanish. However, they do not consent to patients of other languages. They would need an interpreter. They would not feel comfortable in consenting through an interpreter for these procedures. The majority of the patients consented for pain medications. Meds given to lessen pain during procedures. Either the physician or a second nurse, not by the Trainee, provides IV MEDS.

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Regulation: (Section 92310). Costs. A plan for determining estimated or projected costs shall include, but not be limited to the following: (a) An identification of the average cost of preparing a trainee. This shall include cost information related to instruction, instructional materials and equipment, space for conducting didactic and clinical phases, and other pertinent costs. (b) An identification of the average cost per patient visit for similar care rendered by a current provider of care. (c) An identification of predicted average cost per patient visit for the care rendered by a trainee.				Budget Updates. Proforma's Cost of training: administrative, didactic and clinical phases.						No cost data available. Sponsor is analyzing the cost data and will submit upon completion.
Regulation: (Section 92603). Site Visits. Site visits shall include at least the following: (a) Determination that adequate patient safeguards are being utilized. (b) Validation that the project is complying with the approved or amended application. (c) Interviews with project participants and recipients of care. (d) An interdisciplinary team composed of representatives of the healing arts boards, professional organizations, and other State regulatory bodies shall be invited to participate in a site visit.				Observed performance assessment. Procedure Log. Patient complications tracking. Trainee Clinical Schedule. Project Safety committee report.				I was surprised to learn that it is already considered within the current scope of practice for mid-level providers to perform suction aspirations for non-viable pregnancies (miscarriages, incomplete abortions etc.). This assertion was made by the study coordinator and she indicated that this was current practice (outside of the study) in the Shasta area.	At this site, patients are offered IV anesthesia, which they are not at previous site. Appropriate staff is available during procedures as RN is giving IV sedation. At this time there are 13 clinicians consenting, five APCs, 3 in practice and 2 in training. At this site 1 day a week is dedicated for	APC Trainees are on site for their training on Tuesdays of each week. Six to seven weeks are dedicated to the training phase.

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